REMARKS

The Restriction Requirement dated October 15, 2009, has been reviewed and the comments of the U.S. Patent and Trademark Office have been considered. Applicants respectfully request reconsideration based on the following remarks.

1. Claim Status

A detailed listing of all claims that are in the application, irrespective of whether the claims remain under examination in the application, is presented with an appropriately defined status identifier. Claims 1-25 are pending in this application.

The Office objected to claims 13-21, 24 and 25 as being in improper multiple dependent form. Applicants have amended claims 13-21, 24 and 25 to depend from claim 1 and remove any improper multiple dependency. Applicants submit that the amended claims overcome the objection. No new matter has been added by the claim amendments. Applicants respectfully request entry of the amended claims.

2. Restriction/Election

The Office has imposed a restriction of inventions allegedly as not so linked as to form a single inventive concept, and requested that Applicants elect one of the following inventions:

> Group I, claims 1-12, drawn to a diagnostic method for estimating a patient treatment response; or
>
> Group II, claims 22 and 23, drawn to a diagnostic system.

In addition, the Office further imposed a restriction of species on the claims of Group I, and requested that Applicants elect one of the following species:

Species A, claim 2, drawn to where the cut-off value is determined as a function of treatment response data;

Species B, claims 3-6, drawn to where the cut-off value is determined by reference to a pathogen load drop;

- Subspecies (i) of claim 5
- Subspecies (ii) of claim 6

Species C, claims 7 and 8, drawn to where the cut-off value is determined by *Prob of success*.

The Office requires restriction between the groups based on a determination that Group I and Group II do not relate to a single inventive concept because they lack the same or corresponding special technical features. The Office further requires restriction of more than one species alleged to be not so linked as to form a single general inventive concept.

Applicants respectfully traverse. The Office asserts that the "inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason: Group I requires the special technical feature of comparing the fold change resistance value of a pathogen to a clinical cutoff value, whereas Group II does not require this feature. Group II requires comparing the fold change response to a cutoff value, which Group I does not require. Thus, Group I and Group II do not share the same special technical feature and are not related to a single general inventive concept." Office Action at page 2. Applicants submit that the special technical feature of comparing the fold change resistance value of a pathogen to a clinical cutoff value in Group I is a corresponding special technical feature of comparing the patient fold change response to a cutoff value in Group II. Both groups are comparing the fold value to a cut-off value to reach the same technical result, predicting the clinical response to a drug. Applicants therefore submit that, for at least this reason, the inventions of Group I and

Group II do share corresponding special technical features that "define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." PCT Rule 13.2.

In addition, Applicants submit that the species restriction is overly broad and restrictive. In particular, claims 5 and 6 are linked by measuring the individual contributions of factors that influence load drop. Therefore, the claims of Group I and Group II and the delineated species fulfill the requirement for unity of invention, and Applicants request reconsideration of the restriction requirement.

To be responsive should the restriction be maintained, Applicants provisionally elect Group I, and species B to claims 3-6, with subspecies for claim 6. As a result, claims elected for prosecution, subject to the species election, would include claims 1, 3-5, and 9-21. In the Restriction, the Office had not reviewed claims 13-21, 24 and 25. As amended, Applicants submit that claims 13-21 are drawn to the diagnostic method of Group I. Therefore, the claims are identified as elected subject to the restriction.

Applicants' election is made without prejudice. The right to file continuing applications on any non-elected subject matter as appropriate is reserved. As indicated in the Office Action, upon allowance of a generic claim, Applicants will be entitled to consideration of claims to the non-elected species that depend from or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F .R. § 1.141. Office Action at page 3. Currently, claims 1 and 9-12 are generic. Office Action at page 4.

4. CONCLUSION

Applicants submit concurrently a request for a two-month extension of time under 37 C.F.R. § 1.136 with payment by Credit Card for the fees set forth in 37 C.F.R. §§ 1.17(a)(2) in the amount of $490.00. In the event that any additional extension of time is necessary to prevent the abandonment of this patent application, then such extension of time is petitioned. The U.S. Patent and Trademark Office is authorized to charge any additional fees that may be required in conjunction with this submission to Deposit Account Number 50-2228, under Order No. 026038.0265PTUS from which the undersigned is authorized to draw.

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Respectfully submitted,

By _____

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